Express Mail No. EV 432654464 US

REMARKS

Upon entry of this amendment, claims 1, 2, 17-24, 38, 40-49 are pending and under consideration. Claims 3-16, 25-37, 39, and 50 were canceled by this amendment. In cancelling this subject matter from this application, applicants are not conceding the propriety of any rejection made in the pending Office action and applicants expressly reserve the right to pursue the remaining subject matter through one or more divisional applications. The pending claims have been amended consistent with the applicant's election of the Group VI claims in response to the restriction requirement.

I. Objection to Claims 40-48 Based on 37 CFR 1.75(c)

Reconsideration of the objection to the form of claims 40-48 as being improper because a multiple dependent claim cannot depend from any other multiple dependent claim, under 37 CFR 1.75(c), is respectfully requested. In response to this objection, claims 40-48 have been amended to depend from a single claim. Accordingly, the basis for this objection has been removed.

II. Rejection of Claim 38 Under 35 U.S.C. § 112, first paragraph

Reconsideration of the rejection of claim 38 (claim 39 has been cancelled), directed to a composition for inhibiting thrombotic conditions in blood, as being nonenabled, under 35 U.S.C. § 112, first paragraph, is respectfully requested. The test for enablement is whether one reasonably skilled in the art could make or use the invention based on the disclosure coupled with information known in the art, without undue experimentation. MPEP § 2164.01, citing United States v. Telectronics, Inc., 857 F.2d 778, 785 (Fed. Cir. 1988). Contrary to the Office's assertions, the specification of the present invention enables one skilled in the art to make and use the claimed invention without undue experimentation.

In the present Office action, the Office allows that the specification is enabling for inhibiting specific thrombotic conditions e.g., treating deep vein thrombosis. The Office, however, states that the specification is not enabling for inhibiting thrombotic conditions in general. Applicants respectfully traverse this conclusion. The specification describes

thrombosis, generally, as "a pathological process . . . [that] results when platelet aggregation and/or a fibrin clot blocks (i.e., occludes) a blood vessel." (Specification, page 2, line 17). Platelet aggregation and/or fibrin clots are common to specific types of thrombotic conditions. The compositions of the present invention inhibit human coagulation factor TF-VIIA and thereby inhibit the coagulation cascade. Thus, logically, treatment for specific thrombotic conditions would be effective in treating a general class of such conditions having the same etiology.

Further, the Office states that the assays described in the specification at page 202 "merely measure the in vitro inhibition/anticoagulant activity, however, no guidance is provided [as to] how this in vitro data correlates to in vivo [results]." The Office further asserts that the assay data is "insufficient such that no reasonable extrapolation could be made . . . regarding the activity of the myriad of compounds embraced by the structural formula of the claims." According to MPEP §2107.03, citing Nelson v. Bowler, 626 F.2d 853, 857 (C.C.P.A. 1980), "an applicant does not have to prove that a correlation exists between a particular activity [as measured in an in vitro assay] and an asserted therapeutic use of a compound as a matter of statistical certainty, nor does he or she have to provide actual evidence of success in treating humans where such a utility is asserted." MPEP § 2164.02, citing Cross v. Iizuka, 224 USPQ 739 (Fed. Cir. 1985), similarly states that "a rigorous or an invariable exact correlation is not required." And, MPEP §2164.02 states that "for a claimed genus, representative examples together with a statement applicable to the genus as a whole will ordinarily be sufficient if one skilled in the art . . . would expect the claimed genus could be used in that matter without undue experimentation." Thus, it is not necessary that the specification disclose an exact correlation between the in vitro data regarding the inhibition of certain coagulation factors and in vivo results relating to the inhibition of thrombosis generally. And, it is not necessary that one skilled in the art be able to make an extrapolation from the data provided in the representative examples, for exemplified compositions, to the activity of the claimed genus as a whole, because the genus as a whole acts to inhibit the coagulation cascade.

Finally, the Examiner cites two thrombotic conditions, venous thromboembolism and pulmonary embolism, which are either clinically silent or difficult to diagnose, and

states that studies evaluating the efficacy of pharmaceutical agents against such condiction[s] may not be clinically feasible." The examiner further asserts that this establishes that the disclosure could not possibly be "indicative of any pharmaceutical agents that are effective for generally inhibiting all types of thrombotic conditions." However, in Ex Parte Hozumi, 3 USPQ.2d 1059, 1060-61 (Bd. Pat. App. & Int'f 1987), the Board stated that "as to the examiner's . . . rejection based on an asserted lack of enablement with respect to the utilization of the entire genus disclosed in the antitumor utility disclosed: it is not necessary that all of the compounds claimed be useful for *every* utility disclosed in an application." Thus all of the compositions of the present invention do not have to be useful in treating each and every specific thrombotic condition in order for these compositions to be useful in treating thrombosis generally, or the genus as a whole.

Altogether, weighing all the factual considerations discussed above, the specification is enabling for inhibiting thrombotic conditions in general, because undue experimentation would not have been needed in order for one reasonably skilled in the art to make or use the invention.

III. Rejection of Claims 1,2, 17-24 and 38-39 under the Doctrine of Obviousness-type Double Patenting

Reconsideration is requested of the provisional rejection of claims 1,2, 17-24 and 38 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1,2, 17-24 and 38-39 of copending application no. 10/215,292. If the response/amendment places the claims pending in the present application in a condition for allowance and no other objections are raised, then the provisional double patenting rejection would be the sole grounds of rejection for the pending application. According to the MPEP, "[i]f the 'provisional' double patenting rejection in one application is the only rejection remaining in that application, the examiner should withdraw that rejection and permit the application to issue as a patent, thereby converting the 'provisional' double patenting rejection in the other application(s) into a double patenting rejection at the time the one application issues as a patent."

Express Mail No. EV 432654464 US

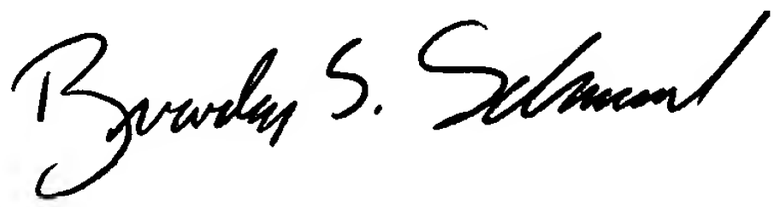
MPEP '804(I)(B). Thus, the present application should be allowed to issue as a patent and the provisional double patenting rejection in copending application no. 10/215,292 converted into a double patenting rejection. In the alternative, once copending application no. 10/215,292 has issued as a patent, the provisional double patenting rejection in the present application can be converted into a double patenting rejection. In either scenario, applicants will address the double patenting issue when it is no longer provisional in nature.

Express Mail No. EV 432654464 US

CONCLUSION

In light of the foregoing, applicants request entry of the claim amendments and withdrawal of all claim rejections and objections, and solicit an allowance of the claims. The Examiner is invited to contact the undersigned attorney should any issue remain unresolved.

Respectfully submitted,



Bradley S. Schammel, Reg. No. 54,667
SENNIGER, POWERS, LEAVITT & ROEDEL
One Metropolitan Square, 16th Floor
St. Louis, Missouri 63102
(314) 231-5400

BSS/vlm